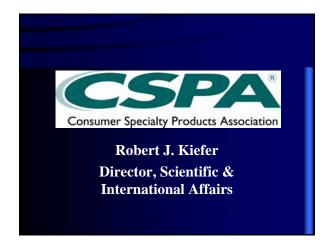
Perspectives on the Value of GHS

GHS OPP Public Stakeholder Meeting Arlington, VA October 18-19, 2006



Perspectives on Value of GHS

Topics

CSPA Approach
Benefits of GHS
OPP White Paper
Scope of Coverage
Industry Response

Perspectives on Value of GHS

CSPA represents manufacturers and formulators of non-agricultural pesticides:

Disinfectants, sanitizers, germicides
Insecticides, repellants, rodenticides
Any pesticide labeled for use in areas "in
or around household premises"
Or for use on pets

Perspectives on Value of GHS

CSPA Approach

Implementation of GHS was not a matter of "IF" and "WHAT" but "WHEN" and "HOW"

Task was how best to implement change in a cost effective, practical and reasonable manner

Perspectives on Value of GHS

CSPA Approach

Ardent supporter of the objectives of GHS Contributed to its development as member of Coordinating Committee on International Harmonization (CCIH)

Recognizes the many anticipated benefits of harmonization that will result from implementation of GHS

However, many of members have concerns about its implementation that <u>must</u> be addressed before proceeding

EPA Implementation of GHS

The Globally Harmonized System of Classification and Labeling of Chemicals: Implementation Planning Issues for the Office of Pesticide Programs

August 25, 2004 - EPA Office of Pesticide Program publishes White Paper Comment period extended to Dec. 6, 2004 EPA Docket OPP-2004-2005

EPA Implementation of GHS

Scope of Coverage

Applies to all types of pesticides
Limit changes to those necessary to
achieve consistency with GHS
Adopt only those GHS hazard
classification criteria and label elements
for all hazard classes for which OPP
currently requires hazard labeling of
pesticide products

EPA Implementation of GHS

Scope of Coverage

All GHS-prescribed label elements (pictograms, signal words and hazard statements) should appear together on the label

Pictograms would include a red border Only one signal word would appear on each label

EPA White Paper: Industry Response

Principles:

Application of Building Block Approach

Limit adoption of GHS to Building Blocks that correspond to existing scope of regulations EPA should continue to exempt indoor residential use products from requirements for labeling environmental endpoints

Consideration of Risk

Base hazard labeling of consumer products on consideration of risk ("likelihood of harm") for chronic effects

EPA White Paper: Industry Response

Principles:

Existing Data and Additional Testing

One Objective of GHS is to reduce the need for testing and evaluation of chemicals and mixtures GHS is based on currently available data Maximize use of existing information for C&L without mandating test methods

EPA should not require submission of additional test data due to shift in classification criteria for some endpoints

EPA should not impose any new test requirements on a product (for purposes of GHS compliance) that were not previously required

EPA White Paper: Industry Response

Principles:

Precedence of Human Data

Human experience should take precedence over other data

Consistent with NAS position regarding use of ethically obtained data from humans

Weight-of-Evidence Approach

Use a weight-of-evidence approach in classification decisions based on best available data

EPA White Paper: Industry Response

Principles:

Data Point Protection for Cite-All and Me-Too Registrations

Protection of Confidential Business Information

GHS calls for disclosure on label of ingredients that contribute to hazard classification
GHS provides that national rules governing disclosure of CBI will take precedence over ingredient disclosure provisions
OPP policies are consistent with GHS

EPA White Paper: Industry Response

Principles:

Focus on requiring information that meets needs of antimicrobial consumer product users

enhance comprehensibility

new GHS requirements must replace, not add to current precautionary statements – reduce clutter align labeling requirements of indoor residential-use antimicrobial cleaning products with CPSC requirements for other consumer products – consistent information

EPA White Paper: Industry Response

Specific Consideration by Hazard Class:

Current EPA Category IV Eye Irritants

- Covers pesticides that result in "minimal effects clearing in less than 24 hours"
- GHS would not classify products with such effects
- OPP plans to propose that these products be considered unclassified

EPA White Paper: Industry Response

Specific Consideration by Hazard Class:

Flammability and Other Physical Hazards

- OPP plans to adopt all GHS hazard classes and categories and corresponding label elements, including use of pictograms and signal words
- OPP would need to adopt each associated test method in OPPTS Series 830 Product Properties Test Guidelines – i.e., aerosol flammability

EPA White Paper

Implementation of GHS

OPP Implementation Options

Pilot Project

Timing and Transition

NAFTA Synchronization/Coordination

Outreach and Education

EPA White Paper

OPP Implementation Options

Option 1: Establish a separate review and approval process; *or*

Option 2: Integrate GHS label changes into on-going registration and re-registration actions

EPA White Paper: Industry Response

OPP Implementation Options

Support for Option 1

Implement in phases by chemical or product category

Competing products in same category labeled according to same set of requirements and timeline

Avoid competitive advantage/disadvantage Maintain competitive level playing field Consider GHS labeling via notification

EPA White Paper: Industry Response

Pilot Project

Proposal to allow for voluntary submission of label amendments with GHS changes by registrants before final rules are in place

Conduct *voluntary* pilot project before proposing amendments to regulation

Assist with determining feasibility of GHS label changes, realistic timelines and regulatory impact Mock label exercise

Economic Impact Analysis – "major rule?

EPA White Paper: Industry Response

Timing and Transition

OPP states that ideally rulemaking could be initiated in 2004 and completed in 2005 (It is now late 2006)

Global implementation goal is 2008

Suitable transition period (24-36 months)

Stagger deadlines by phasing in requirements by product type, chemical, or chemical class

Treatment of existing stock

EPA White Paper: Industry Response

NAFTA Coordination/Synchronization

Consult with NAFTA Partners NAFTA TWG on Pesticides 5-Year Workplan

Designation of USG Lead Agency

GHS Strategy for Implementation "Under TWG, NAFTA countries are committed to implementing the GHS as it relates to pesticides in a coordinated manner"

EPA White Paper: Industry Response

NAFTA Coordination/Synchronization

Canada

Pest Control Products Sector Working Group PMRA Summary Discussion Document (April 2005)

NAFTA Coordination

Comparison Document (December 2005)

Identify differences in proposed approaches

EPA White Paper: Industry Response

Outreach and Education

Education and training is key Awareness-raising activities with OPP stakeholders (e.g., PPDC, SFIRIG)

Creation of industry stakeholder group Conduct public stakeholder meetings and workshops

Explore work sharing opportunities with States

EPA White Paper: Industry Response

Concerns

Exempt pesticides from GHS

Pesticides are registered and marketed domestically, not internationally

Pesticides exempt from HazCom

FIFRA is a risk based regulation

Move from current 3-Signal Word System (Danger, Warning, Caution) to 2-Signal Word (Danger, Warning) under GHS

Products will be "re-classified" as more toxic

EPA White Paper: Industry Response

Concerns

Resulting impact to product classification will lead to changes in:

Pesticide training programs reference materials

Worker protection standards

Applicator training

Personal protective equipment (PPE) recommendations

State regulations

Statutory requirements

Commercial preference for products with "Caution

Loss of market

EPA White Paper: Industry Response

Concerns

Product Re-testing

Label Costs for revising (colors, pictograms)

Amount of information on labels needs to be reduced (40 CFR 156 and Label Review Manual)

Environmental hazard symbol on end-use products

Maintain level playing field

Lack of pubic stakeholder participation



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